

REMARKS

The Examiner has withdrawn from further consideration Claims 34-36, as well as Claims 6-12 and 14-20, which had been amended to depend from Claims 34-36. 37 CFR 1.142(b) and MPEP § 821.03. Applicant, however, respectfully traverses this action.

The Examiner states that the new claims are “directed to an invention that is independent or distinct” from that originally claimed because it recites a “method of lung treatment.” This is not a rationale and it is not understood what the particulars of the perceived distinction may be, why terminology in the claim preamble is being construed as such a distinction and, above all, why this perceived distinction involves a “different search” from that already performed with respect to claims reciting “a method of treating respiratory disorders.”

Applicant submits the Examiner’s holding fails to establish support for his contention that election and/or withdrawal is required. As such, the Examiner is requested to withdraw the requirement and examine all outstanding claims.

In addition, the Examiner has rejected Claims 1-3, and 5 under 35 U.S.C. §102(b) as anticipated, and has rejected Claims 21-24, 26, 27 and 30 under 35 U.S.C. §103 (a) as rendered obvious, by the disclosure of U.S. Letters Patent No., 5,633,003, issued to Cantor (“Cantor”) in view of the disclosure of U.S. Letters Patent No. 5,376,386, issued to Ganderton et al. (hereafter “Ganderton”). Applicant respectfully traverses the rejection, for the reasons which follow.

Claim 21 had been amended previously to identify the formulation as further comprising a drug, thus incorporating the limitation of claim 25, which claim had been allowed by the Examiner. Claims 26, 27 and 30 all had been amended to depend from claim 21.

With the rejection of these claims, the Examiner has completely reversed his position with respect to claims he previously allowed, and has given no reason whatsoever why his initial examination of all outstanding claims had been deficient or that reconsideration was required by any amendment submitted with respect to the claims presently under rejection. Apparently, Applicant's amendments, taken in reliance on the Examiner's pronouncement that Claim 25 had been allowed, were merely a new starting point for citing more art and other grounds for rejection, all of which the Examiner should have considered in his initial examination.

Moreover, in the present rejection, the Examiner has also specifically contradicted his earlier findings wherein he detailed in his reason for allowance of Claim 25, among other claims, that the "present invention" possessed differences which included "specific molecular weights and concentration that are unobvious to those of the prior art, and that are not suggested or taught by the prior art document." Official Action of August 1, 2003, at page 7. This is especially astounding where the instant rejection references no disclosure in Ganderton of such weights and concentration. Nonetheless, somehow, the Examiner considers both Cantor and Ganderton as motivating one all the same to use the specific weights and concentrations as are claimed. Needless to say, Applicants respectfully and totally disagree.

It is Applicants view that the course of prosecution in this matter has digressed. Claims once allowed and now under rejection, despite acknowledgement that claim elements, formerly considered illustrative of unobviousness, remain still unaccounted for in the newly cited combination, only demonstrate the instant rejection utterly lacks support. Such piecemeal examination, furthermore, should not stand.

With respect to other particulars of the rejection, as Applicants shall demonstrate, the Examiner has seemingly extended Cantor as a cite against claims to subject matter formerly deemed allowable, by combining Cantor with Ganderton. As is clear, however, from the rationale the Examiner now apparently relies upon, such application of Cantor is misplaced and does not support a *prima facie* case of obviousness.

The Examiner cited Cantor in both the present and the former rejections for disclosing administration of a polysaccharide, in particular hyaluronic acid. Ganderton is presently cited in combination with Cantor to disclose use of “a polysaccharide and bronchodilator drugs” used as an inhalant.

The rejection, and its asserted combination of citations, however, fails to adequately consider the actual disclosures of the cited references. Ganderton does not teach or suggest combination of bronchodilator drugs with the hyaluronic acid of Cantor. Indeed, Ganderton discloses that “preferably the carrier comprises *crystalline sugar or sugar alcohol* which has a *low affinity for water*, for example, dextrose, fructose, sucrose, or *most preferably* lactose.” If it is the Examiner’s contention that hyaluronic acid is a polysaccharide which shares the characteristics referenced in Ganderton as preferred, or, as would be more appropriate to determining “obviousness”, referenced as “most” preferred, the Examiner should so elaborate. It is Applicant’s contention that it does not, and that Ganderton teaches away from combination with Cantor. Applicant submits it is not by accident that Ganderton does not reference hyaluronic acid, likely because certain of its properties, including its known relatively high affinity for water, do not fit within the parameters disclosed as preferred, let alone most preferred, in Ganderton. To wit, Ganderton references use of “polysaccharides” in the context of

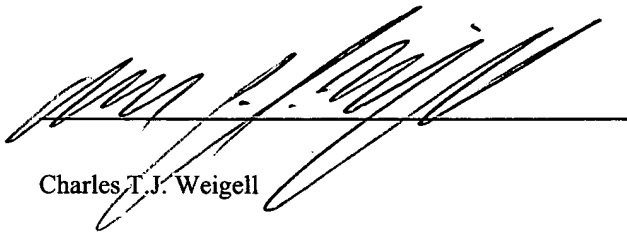
carriers that are to be as “dry as possible prior to encapsulation”, given this Applicants are at a loss as to how the disclosure of Cantor meets these stated objectives in Ganderton.

Hence, the proposed combination of Ganderton and Cantor is not suggested or motivated, nor is the proposed combination been shown to be satisfactory for the purpose asserted. *In re Ratti*, 270 F.2d 810 (CCPA 1959). Indeed, as shown above, Ganderton instead teaches away from use of hyaluronic acid, as disclosed by Cantor. *In re Vaeck*, 947 F.2d 488 (Fed.Cir. 1991). These deficiencies, and the divergent teachings apparent in Ganderton, demonstrate that there is no support establishing the asserted combination with Cantor so as to arrive at Applicant’s claims. Given this, the rejection is improper and should be withdrawn.

Applicants submit that all issues raised by the Examiner have been addressed.

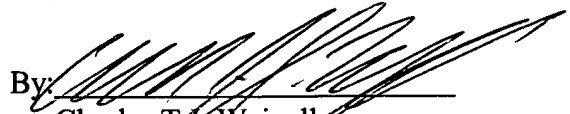
Consequently, Applicants seek reconsideration and withdrawal of all claim rejections, and consideration and allowance of all claims, including those the Examiner has withdrawn.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 23, 2004.



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